

47. (Amended) A preservative formulation comprising a synergistic mixture

of:

- G2
- (a) dehydroacetic acid or a salt thereof;
  - (b) a benzethonium salt;
  - (c) salicylic acid or a salt thereof.
  - (d) benzoic acid or a salt thereof;
  - (e) phenoxyethanol; and
  - (f) benzyl alcohol.

Please add new claim 51 reading as follows:

51. A preservative formulation comprising a synergistic mixture of:

- G3
- (a) a benzethonium salt; and
  - (b) at least one of
    - (i) dehydroacetic acid or a salt thereof, and
    - (ii) salicylic acid or a salt thereof.

### REMARKS

Reconsideration of this application is requested. Claim 1 has been amended to correct the definition of  $R^4$ .  $R^4$  previously was defined as  $-R^5(O)_n(C_6H_5)R^6$ ; however, this definition included 7 substituents on the phenyl group.  $R^4$  is now defined as  $-R^5(O)_n(C_6H_4)R^6$ . Claim 45 has been amended to recite that the composition of claim 1 is applied to a substrate on which microbial growth is to be inhibited. Support for the amendment to claim 45 is found

at page 10, line 25, to page 11, line 3, of the specification. Claim 47 has been rewritten in independent form. Applicant respectfully submits that claim 47 has not been narrowed by this amendment. In the March 3, 2003 Office Action, the Examiner indicated that claims 47-50 would be allowed if rewritten in independent form. Claims 48-50 depend on claim 47. Claim 51 has been added. Support for claim 51 is found, for example, at page 2, lines 5-26; page 4, lines 14-16; page 6, lines 17-18; page 7, lines 6-19; and original claim 24. Claims 1-51 are pending. Claims 2, 3, 7-10, 13, 15-17, 19-21, 23, 28-31, 44, and 45 have been withdrawn from consideration. Accordingly, claims 1, 4-6, 11, 12, 14, 18, 22, 24-27, 32-43, and 47-51 are at issue.

In the March 3, 2003 Office Action, the Examiner states that since a specific benzethonium salt was not elected in the prior response, methyl benzethonium chloride has been treated as the elected salt.

In the September 9, 2002 Response, applicant elected benzethonium salt as the quaternary ammonium biocide. Upon request for a specific and complete composition, applicants elected the formulation shown in Example 5 (table 8 on page 18) of the present application. See the December 12, 2002 Response. The formulation in Example 5 includes benzethonium chloride. Therefore, applicant respectfully submits that the elected salt of benzethonium is benzethonium chloride.

Furthermore, applicants note that methyl benzethonium chloride is not a salt of benzethonium. Rather, methyl benzethonium chloride is a salt of methyl benzethonium, which is a derivative of benzethonium.

Claims 6 and 45 have been rejected under 35 U.S.C. §112, second paragraph, as indefinite. The Examiner asserts that the limitation "R<sup>4</sup> is benzyl" in claim 6 lacks antecedent basis. R<sup>4</sup> as amended is defined as R<sup>5</sup>(O)<sub>n</sub>(C<sub>6</sub>H<sub>4</sub>)R<sup>6</sup>. When n is 0, R<sup>5</sup> is methyl and R<sup>6</sup> is hydrogen, R<sup>4</sup> is a benzyl group. Therefore, the limitation "R<sup>4</sup> is benzyl" has proper antecedent basis.

Claim 45 allegedly omits essential steps related to what object the composition is applied to. Claim 45 has been amended to recite that the composition is applied to a substrate.

For the foregoing reasons, applicant respectfully requests withdrawal of this rejection.

Claim 44 has been rejected under 35 U.S.C. 102(b) as anticipated by Galin (U.S. Patent No. 3,236,730). The Examiner asserts that Galin teaches a composition comprising 0.05 to 0.5% methyl benzethonium chloride and 0.5% to 2.0% salicylic acid.

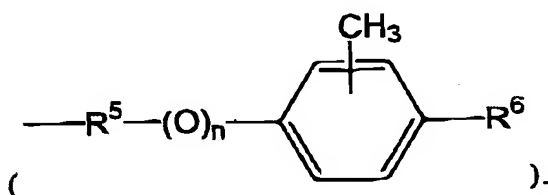
Galin exemplifies a composition containing methyl benzethonium chloride, not benzethonium chloride as recited in claim 44. See col. 37, line 10, of U.S. Patent No. 6,414,032 (a copy of which is attached) for the structure of methyl benzethonium. Methyl benzethonium includes a methyl group on the phenyl group adjacent the diisobutyl group, whereas benzethonium does not. Therefore, Galin does not anticipate claim 44.

Claims 1, 4, 5, 11, 12, 14, 18, 22, 24, 27, 32-43, and 46 have been rejected under 35 U.S.C. §103(a) as obvious over Galin in view of Japanese Patent Publication No. 11279205 ("JP '205"). Galin allegedly teaches a composition comprising salicylic acid and methyl benzethonium chloride for control of ophthalmologic disorders commonly referred to as

blepharitis. JP '205 allegedly discloses ophthalmic aqueous formulations containing dehydroacetic acid and/or sodium dehydroacetate for controlling corneal dryness.

Applicant notes that claim 1 does not encompass methyl benzethonium chloride.

The formula for the quaternary ammonium biocide in claim 1 encompasses benzethonium when  $R^4$  is  $-R^5(O)_n(C_6H_4)R^6$ . The phenyl group in  $R^4$  is substituted at 2 positions. Methyl benzethonium chloride, however, requires that the phenyl group be substituted at 3 positions



As shown in Examples 1 and 2 of the instant application, each of the ketone acids, sodium dehydroacetate and dehydroacetic acid, act synergistically with benzethonium chloride (Hyamine® 1622) against the bacteria *S. aureus*, *P. aeruginosa*, and *E. coli*. Likewise, the aromatic carboxylic acid, salicylic acid, and benzethonium chloride act synergistically against the aforementioned bacteria. See Example 3.

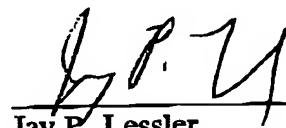
Neither Galin nor JP '205 disclose or suggest the synergism exhibited by combining benzethonium chloride with the ketone acid dehydroacetic acid (or a salt thereof) or the aromatic carboxylic acid salicylic acid (or a salt thereof).

For the foregoing reasons, Galin and JP '205 alone or in combination fail to render obvious the presently claimed invention. Accordingly, applicant respectfully requests withdrawal of this rejection.

In view of the above amendments and remarks, it is respectfully requested that the application be reconsidered and that all pending claims be allowed and the case passed to issue.

If there are any other issues remaining which the Examiner believes could be resolved through either a Supplemental Response or an Examiner's Amendment, the Examiner is respectfully requested to contact the undersigned at the telephone number indicated below.

Respectfully submitted



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Marked-Up Claims  
Accompanying response to March 3, 2003 Office Action  
For U.S. Serial No. 10/087,207  
(Docket No. 5408/11295-US2)

**IN THE CLAIMS:**

1. (Amended) A composition comprising:

- (a) (i) a quaternary ammonium biocide having the formula



- (ii) a polymeric quaternary ammonium biocide, or

- (iii) a mixture thereof; and

- (b) (i) a ketone acid or salt thereof,

- (ii) an aromatic carboxylic acid or a salt thereof, or

- (iii) a mixture thereof,

wherein  $R^1$  and  $R^2$  are independently unsubstituted or hydroxy substituted linear or branched  $C_1$ - $C_4$  alkyl,  $-(CH_2CH_2O)_mCH_2CH_2OH$ , or  $-(CH_2CHCH_3O)_mCH_2CHCH_3OH$  where  $m$  is 1 to 10;  $R^3$  is a substituted or unsubstituted benzyl, ethylbenzyl, methylnaphthyl, or linear or branched  $C_1$ - $C_{22}$  alkyl;  $R^4$  is  $[-R^5(O)_n(C_6H_5)R^6] - R^5(O)_n(C_6H_4)R^6$  where  $n$  is 0 or 1;  $R^5$  is a substituted or unsubstituted  $C_1$ - $C_8$  alkyl or  $C_1$ - $C_8$  alkoxyalkyl;  $R^6$  is hydrogen or a substituted or unsubstituted, linear or branched  $C_1$ - $C_{12}$  alkyl; and  $X^-$  is an anion.

45. (Amended) A method of inhibiting the growth of microorganisms on a substrate comprising applying an effective amount of the composition of claim 1 to the substrate.

47. (Amended) A [The] preservative formulation [of claim 46, further]  
comprising a synergistic mixture of:

- (a) dehydroacetic acid or a salt thereof;
- (b) a benzethonium salt;
- (c) salicylic acid or a salt thereof.
- (d) benzoic acid or a salt thereof;
- (e) phenoxyethanol; and
- (f) benzyl alcohol.

Pending Claims  
Accompanying response to March 3, 2003 Office Action  
For U.S. Serial No. 10/087,207  
(Docket No. 5408/11295-US2)

1. (Amended) A composition comprising:

- (a) (i) a quaternary ammonium biocide having the formula



- (ii) a polymeric quaternary ammonium biocide, or

- (iii) a mixture thereof; and

- (b) (i) a ketone acid or salt thereof,

- (ii) an aromatic carboxylic acid or a salt thereof, or

- (iii) a mixture thereof,

wherein  $R^1$  and  $R^2$  are independently unsubstituted or hydroxy substituted linear or branched  $C_1$ - $C_4$  alkyl,  $-(CH_2CH_2O)_mCH_2CH_2OH$ , or  $-(CH_2CHCH_3O)_mCH_2CHCH_3OH$  where  $m$  is 1 to 10;  $R^3$  is a substituted or unsubstituted benzyl, ethylbenzyl, methylnaphthyl, or linear or branched  $C_1$ - $C_{22}$  alkyl;  $R^4$  is  $-R^5(O)_n(C_6H_4)R^6$  where  $n$  is 0 or 1;  $R^5$  is a substituted or unsubstituted  $C_1$ - $C_8$  alkyl or  $C_1$ - $C_8$  alkoxyalkyl;  $R^6$  is hydrogen or a substituted or unsubstituted, linear or branched  $C_1$ - $C_{12}$  alkyl; and  $X^-$  is an anion.

2. The composition of claim 1, wherein  $R^1$  is  $-CH_2CH_2OCH_2CH_2-$ .

3. The composition of claim 2, wherein  $R^4$  is [2-[2-(4-diisobutylphenoxy)ethoxy]ethyl].



4. The composition of claim 1, wherein the quaternary ammonium biocide is a salt of benzethonium.

5. The composition of claim 4, wherein the quaternary ammonium biocide is benzethonium chloride.

6. The composition of claim 1, wherein  $R^4$  is benzyl.

7. The composition of claim 1, wherein the quaternary ammonium biocide is a salt of benzalkonium.

8. The composition of claim 7, wherein the quaternary ammonium biocide is benzalkonium chloride.

9. The composition of claim 7, wherein the quaternary ammonium biocide is a salt of (C<sub>12</sub>-C<sub>18</sub>) alkyl benzyl dimethyl ammonium.

10. The composition of claim 9, wherein the quaternary ammonium biocide is (C<sub>12</sub>-C<sub>18</sub>) alkyl benzyl dimethyl ammonium chloride.

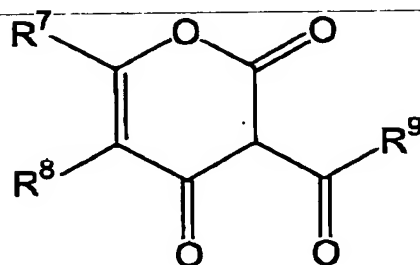
11. The composition of claim 1, wherein  $X^-$  is chloride or carbonate.

12. The composition of claim 11, wherein X<sup>-</sup> is chloride.

13. The composition of claim 11, wherein X<sup>-</sup> is carbonate.

14. The composition of claim 1, wherein the ketone acid is a cyclic ketone acid or a salt thereof.

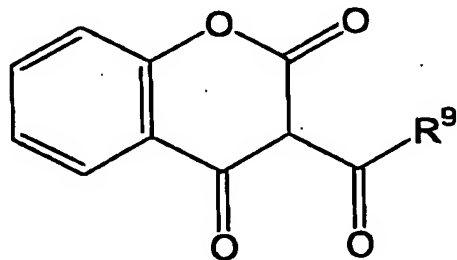
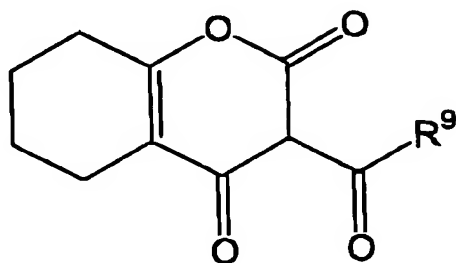
15. The composition of claim 14, wherein the cyclic ketone acid has the formula



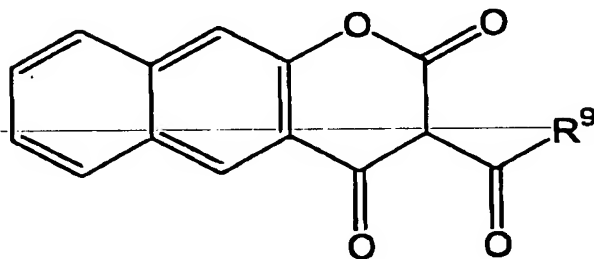
wherein R<sup>7</sup>, R<sup>8</sup>, and R<sup>9</sup> are independently C<sub>1</sub>-C<sub>10</sub> alkyl, C<sub>1</sub>-C<sub>10</sub> alkenyl, C<sub>1</sub>-C<sub>10</sub> alkenyl, aryl, aryl substituted with halogen, or (C<sub>1</sub>-C<sub>10</sub> alkyl)aryl.

16. The composition of claim 15, wherein R<sup>7</sup>, R<sup>8</sup>, and R<sup>9</sup> are independently C<sub>1</sub>-C<sub>4</sub> alkyl; or R<sup>7</sup> and R<sup>8</sup> form a 5-12 member ring.

17. The composition of claim 15, wherein the cyclic ketone acid has the formula



, or



18. The composition of claim 14, wherein the ketone acid is dehydroacetic acid or a salt thereof.

19. The composition of claim 1, wherein the ketone acid is sodium dehydroacetate.

20. The composition of claim 1, wherein the ketone acid is encapsulated.

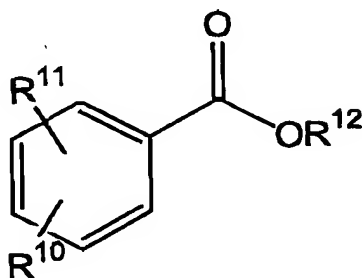
21. The composition of claim 18, wherein the dehydroacetic acid or salt thereof is encapsulated in cyclodextrin.

22. The composition of claim 1, wherein the quaternary ammonium biocide is benzethonium chloride and the ketone acid is dehydroacetic acid or a salt thereof.

23. The composition of claim 1, wherein the quaternary ammonium biocide is benzalkonium chloride and the ketone acid is dehydroacetic acid or a salt thereof.

24. The composition of claim 1, wherein the aromatic carboxylic acid is benzoic acid, derivative thereof, or salt thereof.

25. The composition of claim 1, wherein the aromatic carboxylic acid has the formula



wherein R<sup>10</sup> and R<sup>11</sup> are independently H, -OH, or -OC(O)CH<sub>3</sub>; and R<sup>12</sup> is H, Na, K, Ca, or Mg.

26. The composition of claim 1, wherein the aromatic carboxylic acid is a hydroxy benzoic acid, derivative thereof, or salt thereof.

27. The composition of claim 26, wherein the hydroxy benzoic acid is salicylic acid or a salt thereof.

28. The composition of claim 27, wherein the salt of salicylic acid is sodium salicylate.

29. The composition of claim 1, wherein the quaternary ammonium biocide is benzethonium chloride and the aromatic carboxylic acid is sodium salicylate.

30. The composition of claim 1, wherein the quaternary ammonium biocide is benzalkonium chloride and the aromatic carboxylic acid is sodium salicylate.

31. The composition of claim 1, further comprising a solvent.

32. The composition of claim 31, wherein the solvent is water, an alcohol, a glycol, an ester, an ether, a polyether or any combination of any of the foregoing.

33. The composition of claim 1, wherein the composition comprises a biocidally effective amount of the quaternary ammonium biocide.

34. The composition of claim 1, wherein the composition comprises a fungicidally effective amount of the quaternary ammonium biocide.

35. The composition of claim 1, wherein the weight ratio of the ketone acid to the quaternary ammonium biocide ranges from about 0.00056:1 to about 1990:1.

36. The composition of claim 35, wherein the weight ratio of the ketone acid to the quaternary ammonium biocide ranges from about 0.0056:1 to about 1400:1.

37. The composition of claim 1, wherein said composition comprises from about 0.00005 to about 0.5% by weight of ketone acid and from about 0.00005 to about 0.45% by weight of quaternary ammonium biocide, based upon 100% weight of total composition.

38. The composition of claim 37, wherein said composition comprises from about 0.0005 to about 0.35% by weight of ketone acid and from about 0.0005 to about 0.2% by weight of quaternary ammonium biocide, based upon 100% weight of total composition.

39. The composition of claim 1, wherein the weight ratio of the aromatic carboxylic acid to the quaternary ammonium biocide ranges from about 0.00056:1 to about 1990:1.

40. The composition of claim 39, wherein the weight ratio of the aromatic carboxylic acid to the quaternary ammonium biocide ranges from about 0.0056:1 to about 1400:1.

41. The composition of claim 1, wherein said composition comprises from about 0.00005 to about 0.5% by weight of aromatic carboxylic acid and from about 0.00005 to about 0.45% by weight of quaternary ammonium biocide, based upon 100% weight of total composition.

42. The composition of claim 41, wherein said composition comprises from about 0.0005 to about 0.35% by weight of aromatic carboxylic acid and from about 0.0005 to about 0.2% by weight of quaternary ammonium biocide, based upon 100% weight of total composition.

43. An antimicrobial composition comprising a synergistic mixture of:

- (a) dehydroacetic acid or a salt thereof; and
- (b) benzethonium chloride.

44. An antimicrobial composition comprising a synergistic mixture of:

- (a) salicylic acid or a salt thereof; and
- (b) benzethonium chloride.

45. (Amended) A method of inhibiting the growth of microorganisms on a substrate comprising applying an effective amount of the composition of claim 1 to the substrate.

46. A preservative formulation comprising a synergistic mixture of:

- (a) dehydroacetic acid or a salt thereof;
- (b) a benzethonium salt; and
- (c) salicylic acid or a salt thereof.

47. (Amended) A preservative formulation comprising a synergistic mixture

of:

- (a) dehydroacetic acid or a salt thereof;
- (b) a benzethonium salt;
- (c) salicylic acid or a salt thereof.
- (d) benzoic acid or a salt thereof;
- (e) phenoxyethanol; and
- (f) benzyl alcohol.

48. The preservative formulation of claim 47 comprising:

- (a) from about 5 to about 40% by weight of dehydroacetic acid;
- (b) from about 1 to about 20% by weight of benzethonium chloride;
- (c) from about 2.5 to about 20% by weight of salicylic acid;



- (d) from about 2.5 to about 20% by weight of benzoic acid;
- (e) from about 20 to about 50% by weight of phenoxyethanol; and
- (f) from about 5 to about 50% by weight of benzyl alcohol,

based upon 100% total weight of preservative formulation.

49. The preservative formulation of claim 48 comprising:

- (a) about 10% by weight of dehydroacetic acid;
- (b) about 5% by weight of benzethonium chloride;
- (c) about 10% by weight of salicylic acid;
- (d) about 10% by weight of benzoic acid;
- (e) about 35% by weight of phenoxyethanol; and
- (f) about 30% by weight of benzyl alcohol,

based upon 100% total weight of preservative formulation.

50. A composition comprising from about 0.01 to about 2% by weight of the preservative composition of claim 48.

51. A preservative formulation comprising a synergistic mixture of:

- (a) a benzethonium salt; and
- (b) at least one of
  - (i) dehydroacetic acid or a salt thereof, and
  - (ii) salicylic acid or a salt thereof.